Advanced Cell and Gene Therapy Manufacturing Logistics Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

The field of Advanced Cell and Gene Therapy (CGT) represents a revolutionary frontier in medicine, offering potentially curative treatments for complex and rare diseases, including various cancers and genetic disorders. This rapid expansion, however, is met with unique and formidable logistical challenges that threaten product quality, patient safety, and commercial viability. Unlike traditional pharmaceuticals, CGT products involve living biological materials often patient-specific or donor-derived which demand an unbroken ultra-cold chain, meticulous Chain of Identity (CoI), and real-time tracking. The logistics landscape is characterized by high-stakes complexity, necessitating specialized knowledge in areas like cryogenic transportation, end-to-end digitization, and stringent Good Manufacturing/Distribution Practices (GMP/GDP). The commercial success and patient accessibility of these life-saving treatments hinge entirely on developing a highly skilled workforce capable of navigating this intricate vein-to-vein supply chain.

Advanced Cell and Gene Therapy Manufacturing Logistics Training Course provides a comprehensive and practical deep dive into the specialized manufacturing and logistics orchestration required for commercial-scale CGT operations. It is designed to equip professionals with the cutting-edge skills and strategic insights necessary to manage the entire Cell & Gene Supply Chain with precision and compliance. Key topics include optimizing process development and scale-up, implementing digital solutions for enhanced traceability and visibility, and mastering the management of temperature-sensitive materials from apheresis/collection through to final patient infusion. By focusing on risk mitigation, regulatory harmonization, and the latest industry trends like decentralized manufacturing, this program directly addresses the critical industry need for robust, cost-efficient, and patient-centric logistics solutions, positioning participants as Advanced Therapy Medicinal Products (ATMP) logistics experts.

Programme Curriculum

Advanced Cell and Gene Therapy Manufacturing Logistics Training Course

Introduction

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Course Duration

10 days

Course Objectives

Upon completion of this course, participants will be able to:

1. Master the complexities of the vein-to-vein CGT supply chain, covering both autologous and allogeneic workflows.
2. Apply current Good Manufacturing Practices (GMP) for sterile and aseptic manufacturing in CGT facilities.
3. Implement best practices for ultra-cold chain logistics, including cryogenic storage and validation of dry shippers.
4. Ensure complete Chain of Identity (CoI) and Chain of Custody (CoC) integrity using robust tracking systems.
5. Develop effective risk mitigation strategies for temperature excursions, transportation delays, and sample mix-ups.
6. Analyze and optimize Cost of Goods (CoGs) by streamlining manufacturing and logistics processes.
7. Utilize Digital Solutions for enhanced real-time visibility and data analytics.
8. Comply with major global regulatory frameworks governing ATMPs and their distribution.
9. Design and validate robust packaging and transportation protocols for highly sensitive biological materials.

10. Evaluate the strategic roles of Contract Manufacturing Organizations (CMOs) and 3PL Providers in the CGT ecosystem.
11. Understand the principles of process development and scale-up/scale-out for commercial readiness.
12. Troubleshoot common logistics exceptions and implement Corrective and Preventive Actions (CAPA).
13. Explore emerging trends such as decentralized and point-of-care manufacturing models.

Target Audience

1. Logistics & Supply Chain Managers
2. Manufacturing & Process Development Engineers
3. Quality Assurance (QA) & Quality Control (QC) Specialists
4. Clinical Trial & Operations Managers
5. Regulatory Affairs Professionals
6. Case Managers and Patient Coordinators
7. 3PL and Specialty Courier Service Providers
8. Business Development Leaders in the CGT ecosystem

Course Modules

Module 1: CGT Fundamentals and the Vein-to-Vein Supply Chain

- Advanced Cell and Gene Therapy (CGT) Modalities.
- The Critical "Vein-to-Vein" Process.
- Living Drug Product Challenges.
- Key Stakeholders and Ecosystem.
- Case Study: Analysis of an approved CAR-T therapy launch focusing on supply chain mapping.

Module 2: Good Manufacturing and Distribution Practices (GMP/GDP)

- GMP/GDP Principles for ATMPs.
- Aseptic Processing and Cleanroom Operations.
- Raw Material Sourcing and Qualification.
- Quality Management Systems (QMS) in CGT Logistics.
- Case Study: Review of an FDA Warning Letter or audit finding related to CGT sterility/cross-contamination.

Module 3: Chain of Identity (CoI) and Chain of Custody (CoC)

- The Criticality of CoI/CoC.
- Best Practices for Sample Labeling and Reconciliation.
- Implementation of Digital Tracking Technologies.
- Data Integrity and Documentation.
- Case Study: The catastrophic consequences of a simulated CoI breach in a clinical trial scenario.

Module 4: Ultra-Cold Chain Logistics and Cryopreservation

- Principles of Cryopreservation.
- Selecting and Validating Cryogenic Shippers.
- Packaging Design and Qualification.
- Handling Dangerous Goods.
- Case Study: A comprehensive validation exercise for a dry shipper to maintain?êÆ150?êÿC over a 96-hour transit.

Module 5: Logistics Risk Management and Mitigation

- End-to-End Risk Assessment.
- Contingency Planning.
- Exception Management and Triage.
- Insurance and Liability.
- Case Study: Designing a contingency plan for a critical autologous shipment crossing multiple international borders.

Module 6: Digital Solutions and Supply Chain Orchestration

- Real-Time Monitoring.
- Blockchain Technology for CoI/CoC.
- AI and Machine Learning in Logistics.
- Integration and Interoperability.
- Case Study: Implementing an SAP-based digital orchestration platform to connect a CMO, a 3PL, and a treatment center.

Module 7: Biologistics for Clinical Trials

- Phase I-III Trial Logistics.
- Investigational Product (IP) Management.
- Global Trial Network Setup.
- Reverse Logistics.
- Case Study: Overcoming logistical and customs hurdles during a multi-country Phase II clinical trial for a gene therapy vector.

Module 8: Autologous Therapy Logistics Optimization

- Apheresis Collection and Handling.
- Short Turnaround Time (TAT) Management.
- Batch-of-One Complexity.
- Coordinating Patient Scheduling and Manufacturing Slots.
- Case Study: Optimizing the TAT for an autologous CAR-T product to reduce cell stress and manufacturing costs.

Module 9: Allogeneic Therapy Logistics and Scale

- Centralized Manufacturing and Inventory Management.
- Commercial-Scale Distribution Network Design.
- Vector and Starting Material Supply Chain.
- Forecasting and Demand Planning.
- Case Study: Scaling the logistics network for a commercial-stage allogeneic product moving from clinical supply to global launch.

Module 10: Regulatory Harmonization and Global Compliance

- FDA, EMA, and APAC Regulatory Landscape for CGT.
- Import/Export Regulations and Customs Clearance.
- GxP Across Borders.
- The Role of Qualified Person (QP) in Europe.

- Case Study: A comparison of documentation requirements for a single product launch in the US (FDA) vs. EU (EMA).

Module 11: Process Development and Manufacturing Scale-Up

- Scale-Up vs. Scale-Out.
- Closed System Manufacturing and Automation.
- Facility Design and Flow.
- Cost of Goods (CoGs) Reduction Strategies.
- Case Study: Analyzing the cost-benefit of adopting an automated, closed-system platform over traditional benchtop manufacturing.

Module 12: Outsourcing and Partner Management (CMO/3PL)

- Strategic Sourcing and Due Diligence
- 3PL Selection and Management.
- Quality Agreements and Service Level Agreements.
- Performance Metrics and Key Performance Indicators.
- Case Study: Developing a comprehensive SLA with a 3PL partner for temperature monitoring, CoI checks, and exception handling.

Module 13: Decentralized and Point-of-Care (POC) Manufacturing

- The Shift to Decentralization.
- Mobile Manufacturing Units and PODs.
- Logistics for Localized Supply Chains.
- Regulatory Scrutiny for POC.
- Case Study: Evaluating the logistical feasibility and cost savings of a POC manufacturing network leveraging existing hospital pharmacies or blood centers.

Module 14: Post-Approval Logistics and Commercialization

- Inventory and Distribution Strategy Post-Launch.
- Market Access and Payer Challenges.
- Life-Cycle Management of CGT Products.
- Patient Support Programs and Logistics Coordination.
- Case Study: Developing a commercialization logistics plan for a newly approved gene therapy to ensure rapid patient access.

Module 15: Future Trends and Innovation in CGT Logistics

- Advanced Gene Editing Technologies and Logistics.
- New Delivery Systems and Stability.
- Sustainability in Cold Chain.
- Telehealth and Remote Monitoring Integration.
- Case Study: A panel discussion on the projected impact of AI-driven logistics optimization on the CGT supply chain in the next five years.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org **or call** +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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